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have qualified in another, the carrier pays for claims for items sold or rented to beneficiaries during the period the entity qualified as a supplier. If there is evidence of an overpayment, see subpart C of part 405 of this Chapter.

(f) A billing number may be reinstated after revocation when an entity completes a corrective action plan, to which HCFA has agreed, and provided sufficient assurance of its intent to comply fully with the supplier standards.

[57 FR 27305, June 18, 1992]

§ 405.877 Appeal of a categorization of a device.

- (a) HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under §405.203 is a national coverage decision under section 1862(a)(1) of the Act.
- (b) HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under §405.203 is an aspect of an initial determination that, under section 1862 of the Act, payment may not be made.
- (c) In accordance with section 1869(b)(3)(A) of the Act, HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 may not be reviewed by an administrative law judge.

[60 FR 48424, Sept. 19, 1995]

Subparts I-Q—[Reserved]

Subpart R—Provider Reimbursement Determinations and Appeals

AUTHORITY: Secs. 205, 1102, 1814(b), 1815(a), 1833, 1861(v), 1871, 1872, 1878, and 1886 of the Social Security Act (42 U.S.C. 405, 1302, 1395f(b), 1395g(a), 13951, 1395x(v), 1395hh, 1395ii, 139500, and 1395ww).

SOURCE: 39 FR 34515, Sept. 26, 1974, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.1801 Introduction.

(a) *Definitions*. As used in this subpart:

Administrator means the Administrator or Deputy Administrator of HCFA.

Administrator's review means that review provided for in section 1878(f) of the Act (42 U.S.C. 139500(f)) and §405.1875.

Board means the Provider Reimbursement Review Board established in accordance with section 1878 of the Act (42 U.S.C. 139500) and § 405.1845.

Board hearing means that hearing provided for in section 1878(a) of the Act (42 U.S.C. 139500(a)), and §405.1835.

Date of filing and date of submission of materials mean the day of the mailing (as evidenced by the postmark) or hand-delivery of materials, unless otherwise defined in this subpart.

Date of receipt means the date on the return receipt of "return receipt requested" mail, unless otherwise defined in this subpart.

Intermediary determination means the following:

- (1) With respect to a provider of services that has filed a cost report under §§ 413.20 and 413.24(f) of this chapter, the term means a determination of the amount of total reimbursement due the provider, pursuant to § 405.1803 following the close of the provider's cost reporting period, for items and services furnished to beneficiaries for which reimbursement may be made on a reasonable cost basis under Medicare for the period covered by the cost report.
- (2) With respect to a hospital that receives payments for inpatient hospital services under the prospective payment system (part 412 of this chapter), the term means a determination of the total amount of payment due the hospital, pursuant to §405.1803 following the close of the hospital's cost reporting period, under that system for the period covered by the determination.
- (3) For purposes of appeal to the Provider Reimbursement Review Board, the term is synonymous with the phrases "intermediary's final determination" and "final determination of the Secretary", as those phrases are used in section 1878(a) of the Act.
- (4) For purposes of \$405.376 concerning claims collection activities, the term does not include an action by HCFA with respect to a compromise of

a Medicare overpayment claim, or termination or suspension of collection action on an overpayment claim, against a provider or physician or other supplier.

Intermediary hearing means that hearing provided for in § 405.1809.

- (b) General rule—(1) Providers. The principles of reimbursement for determining reasonable cost and prospective payment are contained in parts 413 and 412, respectively, of this chapter. In order to be reimbursed for covered services furnished to Medicare beneficiaries, providers of services are obliged to file cost reports with their intermediaries as specified in §413.24(f) of this chapter. Where the term "provider" appears in this subpart, it includes hospitals paid under the prospective payment system for purposes of applying the appeal procedures described in this subpart to those hospitals.
- (2) Other entities participating in Medicare Part A. In addition to providers of services whose status as such is indicated in the Act, there are entities (such as health maintenance organizations) that do not meet the statutory test for providers of services, which may also participate in Medicare. These entities are required to file periodic cost reports and are reimbursed on the basis of information furnished in the reports. Although the entities do not qualify for Board review, the rules as set forth in this subpart with respect to intermediary hearings are applicable to the entities to the maximum extent possible, for cost-reporting periods ending on or after December 31, 1971, where the amount of program reimbursement in controversy is at least \$1,000.
- (c) Effective dates. (1) Except as provided in paragraphs (c)(2) and (c)(3) of this section or in §405.1885(e), this subpart applies to all cost reporting periods ending on or after December 31, 1971, for which reimbursement may be made on a reasonable cost basis.
- (2) Sections 405.1835 to 405.1877 apply only to cost reporting periods ending on or after June 30, 1973, for which reimbursement may be made on a reasonable cost basis.
- (3) With respect to hospitals under the prospective payment system (see

part 412 of this chapter), the appeals procedures in §§ 405.1811 to 405.1877 that apply become applicable with the hospital's first cost reporting period beginning on or after October 1, 1983.

[39 FR 34515, Sept. 26, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 48 FR 39834, Sept. 1, 1983; 48 FR 45773, Oct. 7, 1983; 49 FR 322, Jan. 3, 1984; 49 FR 23013, June 1, 1984; 51 FR 34793, Sept. 30, 1986; 61 FR 63749, Dec. 2, 1996]

§ 405.1803 Intermediary determination and notice of amount of program reimbursement.

- (a) General requirement. Upon receipt of a provider's cost report, or amended cost report where permitted or required, the intermediary must within a reasonable period of time (see §405.1835(b)), furnish the provider and other parties as appropriate (see §405.1805) a written notice reflecting the intermediary's determination of the total amount of reimbursement due the provider. The intermediary must include the following information in the notice, as appropriate:
 - (1) Reasonable cost. The notice must—
- (i) Explain the intermediary's determination of total program reimbursement due the provider on the basis of reasonable cost for the reporting period covered by the cost report or amended cost report; and
- (ii) Relate this determination to the provider's claimed total program reimbursement due the provider for this period
- (2) Prospective payment. With respect to a hospital that receives payments for inpatient hospital services under the prospective payment system (see part 412 of this chapter), the intermediary must include in the notice its determination of the total amount of the payments due the hospital under that system for the cost reporting period covered by the notice. The notice must explain (with appropriate use of the applicable money amounts) any difference in the amount determined to be due, and the amounts received by the hospital during the cost reporting period covered by the notice.
- (b) Requirements for intermediary notices. The intermediary must include in each notice appropriate references to law, regulations, HCFA Rulings, or